§ 158.2000 Biochemical pesticides definition and applicability.

This subpart applies to all biochemical pesticides as defined in paragraphs (a), (b), and (c) of this section.

(a) *Definitions*. The following terms are defined for the purposes of subpart U of this part.

(1) A *biochemical pesticide* is a pesticide that:

(i) Is a naturally-occurring substance or structurally-similar and functionally identical to a naturally-occurring substance;

(ii) Has a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of a synthetically-derived biochemical pesticides, is equivalent to a naturally-occurring substance that has such a history; and

(iii) Has a non-toxic mode of action to the target pest(s).

(2) A *Pheromone* is a compound produced by a living organism or is a synthetically derived substance that is structurally similar and functionally identical to a naturally-occurring pheromone, which, alone or in combination with other such compounds, modifies the behavior of other individuals of the same species.

(i) An *Arthropod Pheromone* is a pheromone produced by a member of the taxonomic phylum Arthropoda.

(ii) A *Lepidopteran Pheromone* is an arthropod pheromone produced by a member of the insect order Lepidoptera.

(iii) A *Straight Chain Lepidopteran Pheromone* is a lepidopteran pheromone consisting of an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde, or acetate functional group and containing up to three double bonds in the aliphatic backbone.

(b) *Examples*. Biochemical pesticides include, but are not limited to:

(1) Semiochemicals (insect pheromones and kairomones),

(2) Natural plant and insect regulators,

(3) Naturally-occurring repellents and attractants, and

(4) Enzymes.

(c) *Applicability*. The Agency may review, on a case-by-case basis, naturally-occurring pesticides that do not clearly meet the definition of a biochemical pesticide in an effort to ensure, to the greatest extent possible, that only the minimum testing sufficient to make scientifically sound regulatory decisions would be conducted. The Agency will review applications for registration of naturally-occurring pesticides to determine whether to review the pesticide under this subpart U.

§ 158.2010 Biochemical pesticides data requirements.

(a) Sections 158.2030 through 158.2070 identify the data requirements that are required to support registration of biochemical pesticides. Sections 158.2080 through 158.2084 identify the data requirements that are required to support Experimental Use Permits (EUPs). Variations in the test conditions are identified within the test notes. Definitions that apply to all biochemical data requirements can be found in § 158.2000.

(b) Each data table includes ''use patterns'' under which the individual data are required, with variations including food and nonfood uses for terrestrial and aquatic applications, greenhouse, indoor, forestry, and residential outdoor applications under certain circumstances.

(c) The categories for each data requirement are ''R'', which stands for required, and ''CR'' which stands for conditionally required. Generally, ''R'' indicates that the data are more likely required than for those data requirements with ''CR.'' However, in each case, the regulatory text preceding the data table and the test notes following the data table must be used to determine whether the data requirement must be satisfied.

(d) Each table identifies the test substance that is required to be tested to satisfy the data requirement. Test substances may include: technical grade active ingredient (TGAI), manufacturing-use product (MP), end-use product (EP), typical end-use product (TEP), residue of concern, and pure active ingredient (PAI) or all of the above (All). Commas between the test substances (*i.e.*, TGAI, EP) indicate that data may be required on the TGAI or

EP or both depending on the conditions set forth in the test note.

(e) The data requirements are organized into a tier-testing system with specified additional studies at higher tiers being required if warranted by adverse effects observed in lower tier studies. The lower tier studies are a subset of those required for conventional pesticides, and the studies overall are generally selected from those required for conventional pesticides.

(f) Two sets of guideline numbers are provided for some of the environmental fate data requirements. For ease of understanding, the current guidelines will be used as an interim measure until the new guidelines (in parentheses) are finalized.

§ 158.2030 Biochemical pesticides product chemistry data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of the section.

(2) Definitions in §158.300 apply to data requirements in this section.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use specific.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above.

(d) *Table.* The following table shows the data requirements for biochemical pesticides product chemistry. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Identity and Composition					
880.1100	Product identity and composition	R	TGAI, MP	TGAI, EP	1, 2
880.1200	Description of starting materials, production and formulation process	R	TGAI, MP	TGAI, EP	2, 3
880.1400	Discussion of formation of impurities	R	TGAI and MP	TGAI and EP	4
Analysis and Certified Limits					
830.1700	Preliminary analysis	CR	TGAI and MP	TGAI and EP	5, 8
830.1750	Certified limits	R	MP	EP	6
830.1800	Enforcement analytical method	R	MP	EP	7
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	8
830.6303	Physical state	R	TGAI and MP	TGAI and EP	8
830.6304	Odor	R	TGAI	TGAI	8
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	8, 17
830.6315	Flammability	CR	MP	EP	9
830.6317	Storage stability	R	MP	EP	--